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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,007	12/02/2008	Mario Contorni	PP022095.0003	6488

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
04/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,007	CONTORNI, MARIO	
	Examiner	Art Unit	
	BAO LI	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/13/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-13 in the reply filed on Oct. 13, 2009 is acknowledged.

2. Applicant's election of species (A), CRM197 carrier in the reply filed on Jan 29, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 1-16 are pending. Claims 1-13 within the scope of CRM197 carrier are considered. Claims 14-16 have been withdrawn from consideration.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 4, 8, 9, 10, 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 12-17 of copending Application No. 11,886,556. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference claims comprises all limitations cited in the current claims, although the reference claims are cited comprising other components required by the current claims. Bu the current claims use an open language that do not limit the claimed composition to the cited components.

6. Because the references claims contain all limitations of the current rejected claims, the rejected claims are not considered to be patentable distinct in view of the disclosure of the reference claims in the copending Application.

7. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. An obvious-type double patenting rejection is appropriate where the conflict claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887,225 USPQ 645 (fed. Cir. 1985).

9. **Examiner's note:** The citation of "Hib conjugate has never been lyophilized" is considered to be a product by process, unless Applicant provides evidence this procedure has been made patentable significant difference than the liquid form of "Hib conjugate" possibly reconstituted. Applicants are reminded **that if a product disclosed by a prior art meets the structural limitation, said product will be sufficient to meet the limitations of the claim.** MPEP chapter 2113 cites: Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process

claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process.

Claim Rejections - 35 USC § 102/103

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 4, 8-13 rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 7,348,006B2 to Mario Contormi (A).

12. The applied reference has a common invention, Mario Contorni with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

13. Patent "006B2 disclose that a multivalent vaccine composition is prepared with following non-powder antigens/antigen carrier of out membrane vesicle (OMV) of *Neissera meningitis*, a an antigen from Bordetella pertusis, such as pertusis holotoxin (PT), a tetanus toxoid antigen, preferably the CRM_{197} mutant tetanus toxoid, saccharide antigen from Haemophilus influenzae B conjugate (See entire document, e.g. column 2, claims 2-). Patent "006B2" also teaches that the vaccine is formulated with an adjuvant of aluminum phosphate (See entire document, e.g. column 3) in liquid form. The antigen of the Hib is about 8 to 12 μg. Therefore, the cited reference anticipated claims 1, 4, 8-13.

14. Claims 1, 4, 8-13 rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Applicants No. 2005/0158334A1) to Mario Conterini (B).

15. Mario Conterini et al. (B) disclose a vaccine composition and a method for making the same. The composition comprises antigens including out membrane vesicle (OMV), a saccharide antigen from N meningitis, an antigen from Bordetella pertusis, such as pertusis holotoxin (PT), e.g. CRM_{197} mutant, a tetanus antigen, such as tetanus toxoid, saccharide antigen from Haemophilus influenzae B an antigen from N Meningitis out membrane (See entire document, e.g. [0010-0022], wherein the vaccine is also formulated to comprise an adjuvant of aluminum phosphate (See entire document, e.g. [0059-0061]). Mario et al. 9n (B) also teach that the antigens in the vaccine composition is in liquid without lyophilization. The antigen of the Hib is about 8 to 12 μg. Therefore, the cited reference anticipated claims 1, 4, 8-13.

16. Claims 1, 4-5, 8-13 rejected under 35 U.S.C. 102(b) as being anticipated by Nolan et al. (Vaccine, 2001, Vol. 19, pp. 2127-2137).

17. Nolan et al. describe a new liquid pantavalnet combination vaccine composition, which incorporates a diphtheria, tetanus and whole-cell pertusis vaccine (DTP) with Hib (PRP-OMPC) and hepatitis B vaccine (HB), herein the Hib is Hib capsular saccharide (PRP) is conjugate to N-meningitides outer membrane (OMPC) to form PRP-OMPC conjugate), wherein the Hib antigen is 7.5 μg and OMPC is 125 μg or the Hib antigen is 15 μg and OMPC is 250 μg. Nolan et al. also teach that the multivalent vaccine is prepared with an adjuvant of aluminum phosphate (page 2130). To this context, the cited reference anticipates claims 1, 4, 5, 7-11.

18. Claims 1, 4-5, 8, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan et al. (The Pediatric Infectious Disease Journal, 2002, Vol. 21, No. 2, pp. 138-141).

19. Kaplan et al. describe a new liquid pantavalnet combination vaccine composition, which incorporates a diphtheria, tetanus and whole-cell pertusis vaccine (DTP) with Hib (PRP-OMPC) and hepatitis B vaccine (HB), herein the Hib is Hib capsular saccharide (PRP) is conjugate to N-meningitides outer membrane (OMPC) to form PRP-OMPC conjugate), wherein the Hib antigen is 7.5 μg and OMPC is 125 μg or the Hib antigen is 15 μg and OMPC is 250 μg. To this context, the cited reference anticipates claims 1, 4, 5, 7-11.

20. Claims 1, 4, 8, 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Eskota et al. (A) (LACENT, 1996, Vol. 348, pp. 1688-1692).

21. Eskota yet al. teach a method for immunizing infants with a vaccine composition comprising saccharine antigen of Hib, Tetanus (T) and Pertusis (T), wherein the composition is made Hib saccharide conjugate comprising oligosaccharide conjugated CRM197 mixed with DTP conjugate. The concentration of Hib is about less then 15 μg/ml used (See entire document, e.g. pages 1688-1691). The concentration of the PRP is 1.14 to 11.97 μg/ml, which is less the 15 μg/ml as claims drafted. Therefore, the cited reference anticipates claims 1, 4, 8, 11-13.

22. Claims 1-2, 4, 7, 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Amir et al. (Vaccine 1997, Vol. 2, pp. 149-154).

23. Amir et al. teach a combined tetravalent vaccine, named DTP-PRP-T in liquid form, wherein the Hib antigen is capsular polysaccharide (PRP) conjugate to tetanus, wherein the PRP is 10 μg. Amir et al. also teach using the vaccine composition to vaccine infants by injection in liquid form regardless originally in liquid form or re-constituted as liquid form. Therefore, the reference by Amir et al. anticipates claims 1-2, 4, 7, 11-13.

24. Claims 1-2, 4, 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Boutriau et al. (US Patent Publication No. 2003/0180316A1).

25. Boutriau et al. describe a new liquid multivalent combined vaccine comprising diphtheria, tetanus and whole-cell pertusis vaccine (DTP) with Hib (PRP-OMPC) and hepatitis B vaccine (HB), herein the Hib is Hib capsular saccharide (PRP) is conjugate to the carrier CRM197 in 1-8 μg, preferably 1-5 μg [see entire document , e.g. 0036-0043]. Boutriau et al. teach the PRP-DTP is particularly with aluminum phosphate conjugation [0067]. To this context, the cited reference anticipates claims 1-2, 4 and 7-13.

Claim Rejections - 35 USC § 102/103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

27. Claims 1-7 and 11-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Eskola et al. (THE LACENT 1999, Vol. 354, pp. 2063-2068) and Black et al. (Pedistr. Infet. Dis. 1992, Vol. 12, No. 12, pp. 981-985) in light of the disclosure by US CDC documentation published on line (See attachment).

28. Eskola et al. teach that "The first licensed *Haemophilus influenzae* type b (Hib) vaccine contained the capsular polysaccharide, polyribosylribitol phosphate (PRP) of the organism. Although effective in older children, this vaccine was not protective in children younger than 18 months because of poor immunogenicity and the failure to induce immunological memory. These shortcomings were overcome by chemical conjugation of PRP to T-cell- dependent protein carriers, which allowed B cells stimulated by PRP to interact with T cells to induce immunological memory. Four types of Hib conjugate vaccines with different protein carriers have been licensed: PRP conjugated to diphtheria toxoid (PRP-D), PRP conjugated to tetanus toxoid (PRP-T), oligosaccharide-Hib conjugate conjugated to CRM_{197} (a mutated non-toxic diphtheria toxin [HbOC]), and PRP conjugated to a *Neisseria meningitidis* outer-membrane protein complex (PRP-OMP). Several trials were done, which showed for most conjugate vaccines a highly protective effect. Subsequently, **these vaccines were introduced into many countries,** in which striking decreases in the incidence of invasive Hib disease have been seen. The addition of new antigens to a crowded childhood immunization schedule makes the development of combination vaccines essential. **Since Hib vaccine is generally administered at the same time as diphtheria-tetanus-pertussis (DTP) and other childhood vaccines, development of combined DTP-Hib vaccines was logical. Combinations of Hib conjugate with DTP containing whole-cell pertussis were developed and licensed.** Eskola et al. further concluded that "After the introduction of effective Haemophilus influenzae type b (Hib) conjugate vaccines, clinical practice has driven the development of combination vaccines comprising Hib conjugates with the infant diphtheria-tetanus-pertussis (DTP) vaccines. However, when such combinations contain a cellular pertussis component (Pa), the antibody response to Hib is lower than that with separate injections and doubts have been raised about

their efficacy. We believe that such concerns are unwarranted, since the serological correlates of efficacy previously applied for Hib polysaccharide vaccines seem inappropriate for Hib conjugates. Furthermore, our own studies have shown that the lower antibody responses are not associated with impaired function of the antibodies induced, nor, and possibly more importantly, with the induction of immune memory against Hib. Therefore, with the proviso that careful clinical surveillance of Hib disease is maintained, we encourage the introduction of DTPa-Hib combinations to facilitate the inclusion of Hib into the already crowded childhood immunization schedule." Although Eskola et al. do not explicitly teach that the tetravalent vaccine is in liquid form, the vaccine should be in a vial packaged in a container prior using and taken it out upon using in liquid inherently. Therefore, the reference by Eskola et al. (B) anticipates claims 1-13 inherently.

29. Or alternatively it would have been obvious for any person ordinarily skilled in the art to prepare and stored in liquid form in a seal vial in light of the teaching by Black et al..

30. Black et al. explicitly teach that conclude that such single combined vaccine as a liquid mixture offers the convenience and protection against diphtheria, pertussis, Hib and tetanus without substantial significant change in safety or immunogenicity profile.

31. Applicants are reminded that the combined DTP-Hi in liquid form as Eskola disclosed has been used in US as evidenced by CDC published documentation (See reference W). The Hermetically sealed container such as a vial is a regular practice according to the CDC regulation too in light of the disclosure by Tauxe R (EMERFING INFECTIOUS DISEASE, 2001, Vol. 7, No. 3, pp. 516-521).

32. Therefore, it would have been obvious for any person ordinarily skilled in the art to prepare the DTP-Hb tetravalent vaccine as a liquid formulation in the vial in view of the disclosure by Black et al. and obtain at least same effective immunization efficacy as expected.

33. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

34. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan et al. (Vaccine, 2001, Vol. 19, pp. 2127-2137) or and Robinson (Drugs of Today. 1993, Vol. 29, No. 7, pp. 463-464) or Eskola et al. (THE LACENT 1999, Vol. 354, pp. 2063-2068) and Black et al. (Pedistr. Infet. Dis. 1992, Vol. 12, No. 12, pp. 981-985).

35. Nolan et al. describe a new liquid pantavalnet combination vaccine composition, which incorporates a diphtheria, tetanus and whole-cell pertusis vaccine (DTP) with Hib (PRP-OMPC) and hepatitis B vaccine (HB), herein the Hib is Hib capsular saccharide (PRP) is conjugate to N-meningitides outer membrane (OMPC) to form PRP-OMPC conjugate), wherein the Hib antigen is 7.5 μg and OMPC is 125 μg or the Hib antigen is 15 μg and OMPC is 250 μg. Nolan et al. also teach that the multivalent vaccine is prepared with an adjuvant of aluminum phosphate (page 2130). Nolan et al. do not teach packaging them together in one sealed vial as a liquid mixture and inserting it into a container and taking it out before use the vaccine.

36. Eskola et al. teach that "The first licensed *Haemophilus influenzae* type b (Hib) vaccine contained the capsular polysaccharide, polyribosylribitol phosphate (PRP) of the organism. Although effective in older children, this vaccine was not protective in children younger than 18 months because of poor immunogenicity and the failure to induce immunological memory. These shortcomings were overcome by chemical conjugation of PRP to T-cell- dependent protein carriers, which allowed B cells stimulated by PRP to interact with T cells to induce immunological memory. Four types of Hib conjugate vaccines with different protein carriers have been licensed: PRP conjugated to diphtheria toxoid (PRP-D), PRP conjugated to tetanus toxoid (PRP-T), oligosaccharide-Hib conjugate conjugated to CRM_{197} (a mutated non-toxic diphtheria toxin [HbOC]), and PRP conjugated to a *Neisseria meningitidis* outer-membrane protein complex (PRP-OMP). Several trials were done, which showed for most conjugate vaccines a highly protective effect. Subsequently, these vaccines were introduced into many countries, in which striking decreases in the incidence of invasive Hib disease have been seen. The addition of new antigens to a crowded childhood immunization schedule makes the development of combination vaccines essential. **Since Hib vaccine is generally administered at the same time as diphtheria-tetanus-pertussis (DTP) and other childhood vaccines, development of combined DTP-Hib vaccines was logical. Combinations of Hib conjugate with DTP containing whole-cell pertussis were developed and licensed**. Eskola et al. further concluded that "After the introduction of effective Haemophilus influenzae type b (Hib) conjugate vaccines, clinical practice has driven the development of combination vaccines comprising Hib conjugates with the infant diphtheria-tetanus-pertussis (DTP) vaccines.

However, when such combinations contain a cellular pertussis component (Pa), the antibody response to Hib is lower than that with separate injections and doubts have been raised about their efficacy. We believe that such concerns are unwarranted, since the serological correlates of efficacy previously applied for Hib polysaccharide vaccines seem inappropriate for Hib conjugates. Furthermore, our own studies have shown that the **lower antibody responses are not associated with impaired function of the antibodies induced, nor, and possibly more importantly, with the induction of immune memory against Hib. Therefore, with the proviso that careful clinical surveillance of Hib disease is maintained, we encourage the introduction of DTPa-Hib combinations to facilitate the inclusion of Hib into the already crowded childhood immunization schedule**."

37. Black et al. explicitly teach that conclude that such single combined vaccine as a liquid mixture offers the convenience and protection against diphtheria, pertussis, Hib and tetanus without substantial significant change in safety or immunogenicity profile.

38. Applicants are reminded that the combined DTP-Hi in liquid form as Eskola disclosed has been used in US as evidenced by CDC published documentation (See reference W). The Hermetically sealed container such as a vial is a regular practice according to the CDC regulation too in light of the disclosure by Tauxe R (EMERFING INFECTIOUS DISEASE, 2001, Vol. 7, No. 3, pp. 516-521).

39. Therefore, it would have been obvious for any person ordinarily skilled in the art to prepare the DTP-Hb tetravalent vaccine as a liquid formulation in sealed vial inserted into a container for storage in an appropriate condition and unseal the vial after taken it out from the container prior to vaccinate any subject including a human to obtain a reasonable and expected success in view of the disclosure by Nolan et al. Eskola et al. (B) and Black et al.

40. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

41.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nolan Patrick can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/
Examiner, Art Unit 1648.